

REMARKS/ARGUMENTS

Claims 27-41 remain in this application.

Claims very similar to the claims presented with this Amendment were submitted in a Preliminary Amendment filed on December 17, 2003. However, the present office action was based on the claims as filed and not those presented in the Preliminary Amendment. Per a telephone conversation with the Examiner on December 3, 2008, Applicant's attorney was instructed to file a response to the outstanding office action.

Claim Rejections under 35 USC 101

The rejections under 35 USC 101 have been obviated as the claims now describe "natural looking" sebaceous glands and sweat glands. The term "natural looking" has express support at page 15, line 10 of the "Clean Specification" filed on August 6, 2006. As the claims are directed to a "prosthesis", there is no intention to claim living tissue.

Claim Rejections under 35 USC 103

The claims as presented are directed to an adjustable areola and nipple prosthesis. The prosthesis as claimed provides a number of advantages that are not suggested or described in the cited references.

1. None of the references alone or in combination describe or suggest a prosthetic device that provides for custom cutting and fitting of an areola portion.

The prosthesis as claimed includes at least one circular cut line that allows for a precise and custom fit. The natural areola of a user can range in size and shape. The areola of the device as claimed can be custom sized in diameter to the user's discretion by using circular cut lines as claimed. The ability to customize the size allows for a

precise and custom fit, ability to cover scar tissue, and the ability to provide for cosmetic enhancements.

As indicated by the Examiner, the '321 patent does not describe cut lines as claimed. The '672 patent makes no mention or suggestion of cut lines and does not show any cut lines in its Figures. The Examiner suggests that cut lines are shown in "figures 203 and 3:40". The '672 patent does not include a Figure 203. If the Examiner is referring to Figures 2 and 3, neither Figures 2 or 3 describes a cut line as 20 is a cover, 23 is an inner surface, 28 is a central portion, 30 is a periphery, and 40 are breathing holes. In view of the lack of any discussion of customizing and cutting in either the '321 or '672 patent, the prosthetic device with cut lines as claimed are not obvious in view of these references.

2. None of the references alone or in combination describe or suggest a prosthetic device that provides for custom cutting and fitting of a nipple portion.

None of the references alone or in combination describe a nipple protruding outwardly from a central portion of an areola where the nipple height can be adjusted from about 0.25 to about 1 inch. This feature is much more than a mere design modification as it allows a user a choice of no nipple appearance, to non-erect, to erect, to no protruding nipple.

The '321 patent does not describe a nipple portion as now claimed. The device described in the '321 patent could not be modified to eliminate a protruding nipple portion as it includes a hole (22) disposed longitudinally throughout the nipple portion. In view of the lack of any discussion or suggestion of customizing a nipple portion, and in view of the inability to modify the device described in the '321 patent, the prosthetic device with an adjustable nipple is not obvious in view of the cited references.

3. None of the references fairly describe or suggest rounded natural looking

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sebaceous and sweat glands as claimed.

The '825 patent make no express mention of rounded sebaceous or sweat glands. The Figures of the '825 patent do not seem to show rounded sebaceous or sweat glands and are unclear as to whether the speckled portions of the areola are merely shading, texturing or some type of gland.

A reconsideration and withdrawal of all the present rejections and allowance of all claims is respectfully requested. The Commissioner is hereby authorized to charge any additional fees which may be required in this application under 37 C.F.R. §§1.16-1.17 during its entire pendency, or credit any overpayment, to Deposit Account No. 06-1135.

Respectfully submitted,
FITCH, EVEN, TABIN & FLANNERY

Dated: December 10, 2008



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